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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/181,582	10/28/1998	JOHN JACKSON	110129.416	1072

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/181582

Applicant(s)

JACKSON

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/18/02
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 5, 63-104 is/are pending in the application.
- Of the above claim(s) 101-104 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 5, 63-72, 76-91, 99-100 is/are rejected.
- ☒ Claim(s) 73-75, 92-98 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) #25
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6/14/03  
Claims 1, 5, 63-72, 76-91, 99-100 are rejected under 35 U.S.C. 103(a) as being <sup>CHA et al and</sup> unpatentable over Youxin et al in view of Hunter et al.

Youxin et al teach a composition comprising ABA tri block polymers of polylactic acid and polyethylene glycol (PEG) and a protein (Title) controlled release (abstract). <sup>is specific</sup>

Polymers comprising an excess of polylactic acid over PEG are disclosed (Table 1, page 123).

Cha et al teach delivery of tumor necrosis factor (column 9 line 48) in a vehicle comprising ABA Block copolymers of polylactic acid and PEG (column 7 lines 31-36, 37-42, 61-65).

Hunter et al teach dissolving paclitaxel in methoxypolyethylene glycol (MePEG) <sup>to</sup> 350 prior mixing with a polymer to make a 30:70 MePEG: polymer composition <sup>1</sup> containing 0.2-10% paclitaxel. (col. 60 lines 13-16, 40-41, col. 61 lines 12-13).

It would have been obvious to one of ordinary skill to deliver tumor necrosis factor in the vehicle of Youxin et al for its beneficial effect as an antineoplastic and its deliverability in a triblock polymer vehicle in view of CHA et al and to further deliver paclitaxel <sup>l</sup> in the vehicle of Youxin et al to achieve the beneficial effect of a second antineoplastic in dissolved form. <sup>in view of Hunter et al</sup>

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The disclosure is objected to because of the following informalities: On page 46 line 21 Paclitaxel is misspelled.

Appropriate correction is required.

Claims 1, 5, 63-72, 76-91, 99-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of Hunter et al.

Zhang et al teach a paste composition comprising a triblock polymer of polyethylene glycol and polylactide, and paclitaxel (abstract). 10-40% PEG is specified (Table 1, p. 202).

Hunter et al teach dissolving paclitaxel in methoxypolyethylene glycol (MePEG) <sup>to</sup> 350 prior<sub>ly</sub> mixing with a polymer to make a 30:70 MePEG: polymer composition containing 0.2-10% paclitaxel. (col. 60 lines 13-16, 40-41, col. 61 lines 12-13).

It would have been obvious to one of ordinary skill in the art to add MePEG to the composition of Zhang et al to achieve the beneficial effect of dissolving paclitaxel prior to addition to the polymer in view of Hunter et al.

Applicants argue that Zhang et al does not disclose problems regarding dissolving paclitaxel, therefore, there is no motivation to use the method of hunter et al. However, Zhang et al teach mixing paclitaxel whereas Hunter et al teach dissolving paclitaxel. That is , Zhang et al do not teach dissolved paclitaxel. Applicants presume Zhang et al dissolves the drug, however, Zhang et al does not disclose such.

As to the claimed second drug, addition of a second antineoplastic would be an obvious expedient. In re Kerkhoven 205 USPQ 1069 (CCPA 1980).

As to the claimed liquid or paste, such a property must be inherent in the polymers of Youxin et al and Zhang et al because their polymers are the same as those claimed.

Claims 1, 5, 63-72, 76-91, 99-104 are rejected.

Claims 73-35, 92-98 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
December 6, 2002

  
LAWRENCE E. WEBMAN  
PATENT EXAMINER  
GROUP 1500